STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 October 2004 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change in the name of a manufacturer of the medicinal product	I/01	I	17.09.02	17.10.02
Update of the SPC (point 4.2, 4.4, 4.5, 5.1and 5.2) and PL	II/02	II	19.03.03	26.06.03
Annual reassessment	S/04	S	24.07.03	24.10.03
Change following modification(s) of the manufacturing authorisation(s)	I/05	I	04.07.03	08.07.03
Change in the name and/or address of the marketing authorisation holder	I/06	I	08.08.03	22.09.03
Extension of shelf-life as foreseen at time of authorisation	IB/11	IB	24.10.03	-
Extension of shelf-life or retest period of the active substance	I/12	I	24.10.03	30.10.03
Change(s) to the manufacturing process for the active substance and Quality changes	II/13	II	17.12.03	23.12.03
Update of Summary of Product Characteristics, Labelling and Package Leaflet	II/14	II	29.07.04	13.09.04

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.